UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re MELA Sciences, Inc. Securities Litigation	**Civil Action No. 10 Civ 8774 (VB)**
THIS DOCUMENT RELATES TO: **ALL ACTIONS**	**MEMORANDUM OF LAW**

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF LEAD PLAINTIFF'S MOTION FOR LEAVE TO AMEND THE CONSOLIDATED AMENDED COMPLAINT

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STATUTES

Lead Plaintiff[1], respectfully submits this memorandum of law in further support of its Motion to Amend the Consolidated Amended Complaint ("CAC"), and supplant it with the Proposed Second Consolidated Amended Complaint ("PSCAC").

INTRODUCTION

Lead Plaintiff seeks to amend the CAC to reflect the fact that on November 1, 2011, the FDA granted limited approval of MelaFind for 1.2% of the physician market that Defendants had touted to investors during the Class Period. Defendants' opposition to Lead Plaintiff's Motion concedes that three of the four criteria for denying a motion to amend are not present here. The sole remaining point of contention is whether the proposed amendment to the CAC is futile such that it could not possibly survive a motion to dismiss. This is clearly not the case. The PSCAC presents detailed allegations of undisclosed material flaws and Protocol violations in Mela's critical Phase III clinical trial, which ultimately led to the severely restricted FDA approval of the product on November 1, 2011.

During the Class Period, Mela misled investors by stating that its clinical trial for MelaFind, the Company's flagship product, complied with the binding Protocol Agreement agreed upon with the FDA in advance of the trial. ¶¶ 2-4.[2] Moreover, the Company represented to investors that the results of the MelaFind trial demonstrated 95% sensitivity at the critical 95% lower confidence interval, thereby achieving "***positive top line results***." ¶¶ 60, 117, 119, 122, 132.

These representations were patently misleading. In fact, the MelaFind study and post-study analysis was riddled with flaws, and deviated from the dictates of the Protocol in several

[1] Defined terms are taken from the Memorandum of Law In Support of Lead Plaintiff's Motion to Amend the Consolidated Amended Complaint, filed on November 18, 2011.

[2] All paragraph (¶) references are to the PSCAC unless otherwise noted.

critical respects, such as: 1) the Company utilized only board certified dermatologists in the study, despite the fact that throughout the Class Period, the Company represented that the product would be marketed to both dermatologists and the broader market of "***primary care physicians";*** 2) MELA manipulated its clinical study results in order to meet protocol targets by utilizing an unsound statistical method to analyze and study its data; 3) MelaFind's reported 98% accuracy rate in detecting melanoma skin cancers was falsely enhanced by the fact that every lesion entered into the study was screened beforehand by expert dermatologists and predetermined to be suspicious for melanoma, in violation of the Protocol; 4) MelaFind was unable to test 20% of the lesions presented for melanoma determination, thereby calling into question the safety and efficacy of the device; and 5) the Company's clinical trial violated the Protocol Agreement with the FDA by failing to include the mandated three-month follow-up visits with patients.

Throughout the Class Period, Defendants hid these critical failings from investors, and instead touted the "***positive top line results***" of the study which they claimed "***satisfied the specifications of the Protocol Agreement***", statements which were purposefully tailored to condition investors to believe that a timely and complete FDA approval would be forthcoming. ¶¶ 117, 119, 128, 132, 136, 143, 147. As a result, Mela's stock was artificially inflated.

Investors first learned of the trial's critical flaws on November 16, 2010, when in anticipation of an FDA Advisory Panel Meeting on November 18 (the "Panel Meeting"), the FDA published a scathing critique of the clinical trial, detailing its numerous flaws. ¶ 6, 170. Shareholders were shocked by revelations of the study's gross inadequacies, causing the Company's share price to plummet 54%, from $6.37 to $2.92 per share on high trading volume that same day. ¶ 171. On November 18, 2010, the Advisory Panel Meeting convened in College

Park Maryland. ¶ 45. At the meeting, both the FDA and Panel Members expressed serious concerns regarding the conduct of the study, as well as the efficacy and safety of the device. Only as a result of three critical abstentions, the Panel narrowly recommended approval of the device. ¶ 46. The FDA's scathing criticism of the study and the Panel's tepid endorsement of the product sounded the death knell for a timely and complete approval of the product.

Nearly a year after the Panel Meeting, on November 1, 2011 the FDA finally approved MelaFind, albeit with severe restrictions on its marketability. ¶¶ 4, 114, 177. Specifically, as a direct result of the study's serious flaws, the FDA only approved MelaFind for use by board certified dermatologists. ¶¶ 4, 177. This restriction decimated the available market for the product, as the 8500 dermatologists in the United States represented a ***mere 1.2% of the 700,000 licensed physicians that the Company touted to investors***. ¶¶ 10, 113. This restriction on MelaFind's approval delivered a critical blow to Mela's future revenue prospects. Indeed, indicative of investors' continued disappointment with the limited marketability of the product, the Company's share price currently trades at $4.49 (as of February 7, 2012), well below its $6.37 pre-disclosure price.

As such, the PSCAC provides detailed allegations of Defendants knowing concealment of the clinical trial's numerous critical flaws, the revelation of which caused the Company's share price to precipitously decline. Thus, the PSCAC readily pleads a § 10(b) claim against Defendants, rendering their claim of futility unsustainable. *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001) ("Leave to amend will be denied as futile only if the proposed new claim cannot withstand a 12(b)(6) motion to dismiss for failure to state a claim, *i.e.*, if it appears beyond doubt that plaintiff can plead no set of facts that would entitle him to relief.").

STATEMENT OF FACTS[3]

MELA is a medical device company. Its primary product is a non-invasive, point-of-care instrument called MelaFind, designed to assist in the early detection of melanoma.

The Protocols

In August 2004, Mela delivered a binding protocol to the FDA, designated "Protocol 20031: Evaluation of Pigmented Skin Lesions with MelaFind System," an agreement between Mela and the FDA for the conduct of the pivotal phase III trial to establish the safety and efficacy of MelaFind. ¶ 29. The FDA accepted Protocol 20031, but required that any changes take place only "with the written agreement of the sponsor." *Id.* Despite this clear directive, Mela ***unilaterally changed*** Protocol 20031 in May 2008, and delivered Protocol 20061 to the FDA. ¶ 30. The FDA never officially approved Protocol 20061. ¶ 31. Collectively, Protocols 20031 and 20061 are referred to herein as the "Protocol."

Notwithstanding Mela's ruse, it failed to abide by even its own "amended" protocol. ¶ 31. The pivotal study was riddled with significant Protocol deviations and flaws, both in its conduct and analyses, which made a timely and complete FDA approval highly unlikely. Such flaws were never disclosed to investors during the Class Period.

The Use of Only Expert Dermatologists

In the PMA submitted by the Company to the FDA in June 2009, the stated indication of use for the product was by any "***physician (or properly licensed practitioner)***". ¶ 49. Thus, the Company sought FDA approval of MelaFind for a wide range of health care professionals, including licensed physicians or other "properly licensed practitioner[s]". *Id.* Indeed, throughout

[3] Lead Plaintiff hereby incorporates by reference the Statement of Facts submitted in its Memorandum in Opposition to Defendants Motion to Dismiss, filed on September 23, 2010 ("Opp. to MTD") (Docket # 26), except to the extent the Statement of Facts contained therein references allegations in the CAC which were omitted or amended by the PSCAC.

the Class Period, Defendants touted MelaFind's marketability to "***primary care physicians***" and "***primary care markets in the U.S."*** ¶¶ 120, 148. Yet despite consistently touting MelaFind's marketability to a broad range of health care professionals, it only included board certified dermatologists in the study, who naturally have a significantly higher success rate at diagnosing melanoma than general practitioners, not to mention generically-described "properly licensed practitioners", which include nurses and other non-physician care providers. ¶ 49. As such, MelaFind was tested by an "all star" team of board certified dermatologists, yet sought approval of the device for any primary care physician. *Id.* Thus, the FDA was deprived of any data by which it could analyze MelaFind's efficacy in the hands of non-dermatologists, making it virtually impossible for the FDA to approve the device for the broader primary care market.

The FDA was deeply troubled by this inadequacy in the clinical trial. In the FDA's *Executive Summary*, it determined that:

> [it had] ***no data regarding a study testing the capabilities of MelaFind when used by a physician or health care professional.***
>
> ***
>
> If the FDA review team were to consider approval of use of this device by any physician, then a validated study testing the capabilities of a broader group of physicians in diagnosing atypical pigmented lesions . . . should be included. ***However, the FDA review team has no data from such a study.***

¶ 51. The FDA was no more forgiving at the Panel Meeting. Dr. Rumm, the FDA's expert, opined that the Company used misleading language in defining its proposed indication of use, stating "[t]he Sponsor-proposed indication for use defines user to be a physician or a healthcare provider level. It was only studied with board-certified experts . . . ***The bottom line is that the language is misleading*** . . .." ¶ 52, Exhibit ("Ex.") K, Birnbach Decl., 140.

Several Panel Members voiced similar concerns. According to Dr. Tania Phillips, "the concern is that the study was done in a clinical setting with mainly dermatologists or people trained in dermatology. ***So I am not sure that that—I could state that this has been properly evaluated for the indication they're proposing, which is for physician evaluation."*** ¶ 53, Ex. K, Birnbach Decl., 242. Dr. Collins, whose abstention was pivotal to MelaFind's favorable vote regarding the efficacy and risk/benefit of the device commented: "***I have tremendous concerns about who else might use this and so I would not . . . support this use outside of the dermatology realm***." ¶ 54, Ex. K, 256. In light of this fatal flaw in the study, it came as no surprise that the device was ultimately only approved for use by board certified dermatologists.

Mela's Statistical Gamesmanship

The Protocol required Mela to analyze the trial data using an exact binomial test and to demonstrate that the "95% exact binomial lower confidence bound (ELCB) for sensitivity of MelaFind® to malignant melanomas exceeds 0.95." Ex. A, Birnbach Decl., at 29. Clearing the 95% hurdle for the lower confidence bound using an ***appropriate*** exact binomial test was critical because it means that if the phase III study were repeated, there was only a 5% chance or less that the positive results of the clinical trial were by chance. ¶ 59. Indeed, the 95% Confidence Interval level is a threshold universally utilized by statisticians to establish statistical significance. *Id.* Failure to reach that threshold would be a glaring red flag to the FDA regarding the efficacy and sensitivity of the device. *Id.* Throughout the Class Period, Mela claimed that its phase III study of MelaFind met its primary endpoint by achieving results of "98% sensitivity; lower confidence bound of 95%." ¶ 60. However, Mela failed to disclose that it had used an inappropriate statistical methodology to manufacture these results.

FDA regulations dictate that "each manufacturer shall establish and maintain procedures for identifying ***valid statistical techniques required for establishing,*** controlling, and verifying"

the efficacy of the product under trial." 21 C.F.R. § 820.250. ¶ 57. To calculate an exact lower confidence bound, one must choose a statistical method and then determine whether to conduct a one-sided or two-sided version of that method. The nature and size of a study dictates the statistical method chosen. For example, in a study with a sample size of 40 or more subjects, like the MelaFind trial, a mid-p test is not sufficiently conservative and is generally considered an unacceptable binomial method. Opp. to MTD at 6. For such sample sizes, the Clopper-Pearson and Score methodologies are the accepted methodologies. *Id*. Indeed, on March 13, 2007, well before the onset of the Class Period, the FDA released a document entitled, *Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests* ("FDA 2007 Report"), where it identified Clopper-Pearson as the preferred exact binomial method. *Id*.

Moreover, FDA guidance mandates use of a two-sided approach where trial results could go in one of two directions, e.g. above ***or*** below 95%, as with the MelaFind study. A one sided test is only appropriate where trial results can only go in one direction. *Id.* at 6-7. In fact, since March 2007, well before the onset of the Class Period, FDA guidance advised reporting 95% confidence interval levels utilizing the more rigorous two sided test, as opposed to the unacceptable one sided test. *Id.*

Mela, however, found itself in a quandary. If it utilized the accepted methodologies the FDA advocated, and performed its statistical analysis with the Clopper-Pearson or Score methodologies, it could not achieve the critical 95% threshold. *Id.* at 7. Indeed, even Mela's inappropriate mid-p test did not yield a 95% result when using the two sided approach expressly recommended by the FDA. The FDA's Executive Summary included a chart clearly demonstrating that there was only one possible scenario whereby MelaFind could achieve statistical significance at the Lower Confidence Bound—if the Company utilized ***a mid-P test***

***and* one sided study**—both serious departures from statistical norms. Ex. G, Birnbach Decl., 21. Opp. to MTD, at 7. Rather than risk missing the targeted confidence intervals, Defendants utilized improper methodologies to hit their targets, while boasting to investors of their "top line results" and adherence to FDA requirements. Meanwhile, Defendants kept investors in the dark regarding their use of tenuous statistical methods.

The Company's machinations were ultimately detected by the FDA. At the Panel Meeting, the FDA sharply criticized the Company for its deviant statistical methodology, and concluded: "***Melafind was not statistically better than chance . . . the primary analysis finding of sensitivity was not robust.*** It barely met [the 95% threshold] using one-sided 95% lower confidence bound. ***It would fail if the two-sided 95% lower confidence bound was used***." ¶¶ 67, 98; Ex. K, Birnbach Decl., 135-36. Given the FDA's skepticism regarding the Company's statistical methodology, it was unlikely to hazard approval of the device for anyone other than board certified dermatologists, who were already experts at identifying and diagnosing melanoma.

The Trial Violated the Protocol by Only Including Lesions Suspicious for Melanoma

The PMA sought FDA approval for the device's use on lesions that were not suspicious for melanoma (and therefore did not require immediate biopsy), as well as for suspicious lesions that were to undergo immediate biopsy. ¶ 69; Opp to MTD at 8. To reflect this indication of use, the Protocol required the lesion pool to include both suspicious and non-suspicious lesions. *Id*. The Protocol expressly provided that "***since the use of MelaFind® also includes lesions that are atypical in appearance . . . but that are not undergoing biopsy imminently to rule out melanoma, it is important that the clinical study evaluate these lesions***." ¶ 82; Ex. A, Birnbach Decl., 8. In direct contravention of the Protocol, only those lesions pre-screened by

dermatologists and determined to be suspicious were entered into the clinical trial (and thereafter biopsied). ¶ 70.

In its Executive Summary, The FDA was highly critical of Mela on this issue:

> The FDA review team believes that the clinical data in Protocol 20061 does not support MelaFind use for *the detection of early melanoma* on all atypical lesions (suspicious and non-suspicious for melanoma) since the data is limited to the enrolled atypical lesions suspicious for melanoma. In doing so, the ***FDA review team also believes the sponsor did not adhere to [the] original intent of the Protocol Agreement*** which studied MelaFind on only atypical lesions suspicious for melanoma to rule-out melanoma in order to reduce the number of unnecessary biopsies and not on all atypical lesions (suspicious and non-suspicious for melanoma).

¶ 72. (emphasis added).

The Protocol's requirement to include non-suspicious lesions was critical, as it would ensure that the body of clinical study participants mirrored the population at large and would test MelaFind over the wide range of skin lesions encountered in the general public – rather than just those lesions already identified as suspicious by dermatologists. ¶ 69. Simply put, the Protocol reflected the reality that MelaFind's efficacy could not be adequately tested on a pool consisting solely of lesions pre-selected as suspicious for melanoma, as MelaFind would more easily identify such lesions as melanomas, thereby tainting the study in the Company's favor. *Id.* In order to truly test the efficacy of the product, the trial needed to include lesions that were not suspicious for melanoma in order to determine if MelaFind could accurately discern between melanomas and benign lesions. *Id.* The exclusion of lesions not deemed suspicious for melanoma had the effect of artificially increasing MelaFind's *sensitivity*. ¶ 70. Moreover, inclusion of only those lesions previously diagnosed as suspicious by dermatologists made it highly unlikely that the FDA would approve the device for non-dermatologists.

MelaFind was Unable to Read an Alarming Percentage of Enrolled Lesions

MelaFind could not evaluate 20% of the lesions enrolled in the study, thus calling into serious question the efficacy and safety of the device. ¶ 101. Even more troubling, ***twenty-seven unevaluable lesions were dermatopathologically diagnosed as melanoma.*** ¶ 102. This high unevaluable rate created a real risk that a practitioner using MelaFind could fail to diagnose a fatal melanoma due to its inability to evaluate the lesion. According to Dr. Guarino M.D.[4], a leading expert on the standards and regulations promulgated by the FDA for the drug and medical device approval process, "[t]he inability of MelaFind to read —let alone diagnose accurately—a significant number of lesions calls into question whether this device is useful under any circumstances. MelaFind cannot read every fifth lesion presented to it. Suppose that fifth lesion is a melanoma." ¶ 105. The FDA was similarly concerned about the high unevaluable rate. Dr. Peter Rumm, the FDA representative at the Panel Meeting, commented:

> [MelaFind] was only studied with board-certified experts. ***Importantly, even in the series of expert academic dermatological centers, one-fifth of melanomas could not be detected or evaluated or had problems. In the real world, it may be worse***.

¶ 52; Ex. K, Birnbach Decl., 140, 287. The FDA was particularly concerned about the implications of this high unevaluable rate on the safety of the device. As one FDA expert commented, "***these clinical findings alone raise, in our Agency's view, strong safety and efficacy issues***." ¶ 104; *Id*. at 287. Such a high unevaluable rate raised obvious concerns

[4] Dr. Guarino is also President of Oxford Pharmaceutical Resources, Inc., author of the definitive text on FDA clinical and regulatory standards – *New Drug Approval Process* – and an eminent professor and advisor to the pharmaceutical and medical device industry on FDA applications for over 40 years. Dr. Guarino reviewed the following documents related to the MelaFind phase III trial: Protocols 20031 and 20061; the MelaFind PMA Executive Summary; the FDA Panel meeting transcript; MelaFind Safety and Effectiveness Data; MelaFind Indications for Use; MelaFind Product Literature; MelaFind Pre-Pivotal Clinical Studies Report; MelaFind Pivotal Clinical Study Report; and the Points of Disagreement Between FDA and Mela Sciences.

regarding the safety of the device in the hands of a non-dermatologist, who might miss a melanoma because of MelaFind's failure to read the lesion. Yet despite the obvious import of this staggering unevaluable rate, Defendants not only failed to disclose this fact to investors, they affirmatively touted the trial's "***positive top line results***" throughout the Class Period.

Failure to Perform the Critical Three Month Follow Up

A stated indication of use for MelaFind was to screen lesions which were atypical, yet not suspicious for melanoma, and therefore not slated to undergo immediate biopsy. The Protocol thus required that, "Since the intended use of MelaFind also includes lesions that are atypical in appearance . . . but that are not undergoing biopsy imminently to rule-out melanoma, ***it is important that the clinical study evaluate these lesions***." ¶ 82. (Emphasis added). Moreover, the parameters of the clinical study specified that: "[l]esions in the follow-up arm of the study will be imaged with MelaFind at the first visit (baseline) ***and 3 months later***." *Id.* Page 36 of the Protocol, which summarized the analyses to be performed in the study, noted that one of the analyses would be "***incorporating lesions biopsied at 3-month follow-up***" (emphasis added).

Despite this clear directive, the Company failed to include any three month follow up arm in the study. Instead, the Company allowed dermatologists to biopsy ***every*** enrolled lesion, even those that MelaFind deemed benign. ¶ 83. By foregoing this requirement, the Company simply could not demonstrate to the FDA that MelaFind did not label inactive melanomic lesions benign, which thereafter became malignant, thereby depriving the FDA of critical data regarding the sensitivity of the device. ¶ 84.

The FDA was scathing in its criticism of the Company for failing to conduct the three month follow up, stating in its *Executive Summary*:

> The sponsor initially proposed that "Uncertain" lesions from the . . . "Not Melanoma" [category] that are NOT biopsied would be followed . . . . However, no follow up group was enrolled.

> ***(FDA review team analysis: This group would have provided information on the collection of specific clinical, historical, and dermoscopic information that would have been useful in further characterizing the lesions in the "Uncertain" category.)***.

¶ 85. (Emphasis added).

The *FDA Executive Summary* concludes:

> ***By not providing the 3-month follow up group, the FDA review team have determined that the sponsor has not met Point 1 of the Protocol Agreement: The study inclusion and exclusion criteria are appropriate*** . . . .

¶ 86. (Emphasis added).

Thus, given the abject lack of data regarding the ability of MelaFind to detect inactive melanomas, the FDA was highly unlikely to entrust the device to a non-dermatologist. At the Panel Meeting, FDA statistician, Bipasa Biswas, agreed, stating: "MelaFind was evaluated only on biopsied lesions. ¶ 91. ***So the FDA review team has significant concerns that this device has not been studied adequately for its currently proposed indication for use and therefore may put the health of the public at risk***." *Id.* Throughout the Class Period, the Company failed to disclose this missing vital component of the study, reassuring investors that "***the pivotal trial satisfied the specifications of the Protocol Agreement***." ¶ 132.

The March 2010 Denial Letter

In March 2010, the FDA sent the Company a letter advising it that MelaFind was "unapprovable" in light of the clinical trial's egregious flaws and departures from the Protocol (the "March 2010 Non-Approvable Letter"). ¶ 37. The Company never disclosed the exact contents of the letter. ¶ 40. Despite the serious concerns raised by the FDA, the Company continued to represent to investors that it had conformed to the Protocol. In its press release regarding the non-approvable letter dated March 24, 2010, the Company misleadingly asserted that "***we believe our data satisfy the study's agreed-upon endpoints and we will continue to***

work with the agency to move the approval process forward," omitting any mention of the concerns expressed by the FDA regarding the results and conduct of the trial. ¶ 40, 153.

The Advisory Panel Meeting

Its future in serious doubt after receiving the non-approvable letter, Mela requested an "FDA Panel" to conduct a "formal review and recommendation" pursuant to the Safe Medical Devices Act of 1990 (the "SDMA"). ¶ 42. The Panel was comprised of dermatologists who held a public meeting on November 18, 2010 and heard presentations from the FDA and the Company. ¶ 44-5. The voting members of the Panel were not FDA employees. Its ultimate recommendation was merely advisory and not binding on the FDA. *Id.* The Panel spent the entire day examining the safety, efficacy, risks, and benefits of MelaFind, as well as the legitimacy and robustness of the Company's clinical trial. ¶ 45.

At the Panel Meeting, The FDA's questions, comments, and observations regarding MelaFind, particularly with respect to the Company's clinical study – were damning. *Id.* The independent Panel members were similarly skeptical of the conduct of the trial and the Company's statistical analysis. In fact, what emerged from the Panel meeting was that the Company's clinical trials contained numerous material departures from the Protocol, rendering a timely and unrestricted FDA approval highly unlikely. *Id.* The FDA presenters were unanimous in their criticism of MelaFind and the clinical trial. ¶ 46. Indeed, the FDA summed up its presentation by stating: "***The FDA review team recommends that this device needs a new prospective study***" before it can receive any approval. *Id.*

The Panel members also harbored serious doubts regarding the safety, benefit and efficacy of MelaFind. *Id.* By the slimmest of margins, it voted 8 in favor, 7 against, and 1 abstention on the all-important risk to benefit vote. *Id.* With respect to the effectiveness of the device, 8 voted yes, and 6 voted no, with 2 abstentions. MelaFind's reliance on these abstentions

to secure a Panel recommendation underscored the frailty of its PMA application. As Dr. Connor, a Panel Member who abstained on both the efficacy and risk versus benefit votes explained, "[s]o ***my overall intuition was to vote no*** . . . but I think Dr. Phillips and Dr. Burke felt, and some other members of the panel, it turned that no into an abstain saying there is a lot we don't know about this device . . . ***so that's why my no was an abstain***." Ex. K, Birnbach Decl., 317 (emphasis added).

The Truth is Revealed

On November, 16, 2010, in anticipation of the Panel Meeting, the FDA published its findings regarding the MelaFind study, including its Executive Summary, which offered a scathing review of both the study's flaws and statistical analysis. ¶ 170. The market was shocked to learn of the depth of the trial's inadequacies. Moreover, investors were concerned about the impact that an FDA rejection or limited approval could have on the Company. As reported by *Reuters* in an article entitled, "UPDATE 3–FDA reviewers criticize Mela skin cancer device":

> "The FDA review team has ***significant concerns this device has not been studied adequately for its current indications for use and therefore puts the health of the public at risk,"*** the U.S. Food and Drug Administration said in documents released on Tuesday.

Id. (Emphasis added). Indeed, the FDA's criticisms of the study made it clear that any approval of the device would only be forthcoming after further lengthy delay, and would be severely restricted in scope. The Company, however, could hardly afford further delay in the marketing of MelaFind®. With only $35 million in cash and no other products to drive prospective revenues, there was serious concern amongst investors as to whether the Company could continue as a going concern. In the words of one analyst: "***This now comes down to two main questions—does Mela have enough resources to address the issues, and if not, what is the salvage value of the Company.***" ¶ 170.

Absorbing the full import of the FDA's concerns, Mela's stock price fell approximately 60% over two days, from $6.37 to $2.53, on extraordinarily high volume. ¶ 171. This staggering drop reflected investors' realization that a timely approval for MelaFind would not be forthcoming, and if approved, the market for the product would likely be a fraction of what it had previously anticipated.

The FDA Issues a Highly Restricted Approval of MelaFind

In March 2011, in light of the FDA's stated skepticism regarding the use of the device by non-dermatologists, the Company revised its PMA to allow for use by only board certified dermatologists. As such, the marketability of the device was now cut to ***1.2%*** of the market it had previously touted to investors. ¶¶ 10, 113. As a result of this substantial revision, on September 26, 2011, MELA publicly announced that the FDA had issued an "Approvable Letter" for MelaFind. On November 1, 2011, nearly a year after the Panel Meeting, the FDA approved MelaFind, but only for use by board certified dermatologists who successfully completed training with the device. ¶¶ 4, 114, 177. This restriction was drastic. Since only 8500 of the 700,000 licensed physicians in the United States are board certified dermatologists, the FDA's restriction represents a radical constriction of the potential market and revenues available to the device. Indeed, upon disclosure of this limited approval by the FDA, the price of MELA common stock rose by merely 3% to $5.56, 13% below its $6.37 closing price on November 15, 2010. ¶ 178. Currently its share price trades at $4.35 (as of February 8, 2012), indicative of the limited revenue stream available from MelaFind in light of the FDA's limited approval. As such, the November 1, 2011 "approval" of MelaFind was a ***de facto rejection*** of the PMA the Company originally submitted and touted during the Class Period, as MelaFind simply could not be used by its intended market—licensed physicians and other health care professionals.

The amendments to the CAC are therefore far from futile and set forth allegations which adequately state a Section 10(b) claim sufficient to survive a Rule 12(b)(6) motion to dismiss.

ARGUMENT[5]

Courts liberally grant motions to amend unless "the party seeking leave has acted in bad faith, there has been an undue delay in seeking leave, there will be unfair prejudice to the opposing party if leave is granted, or the proposed amendment would be futile." *See Brecher v. Citigroup Inc.*, 2011 U.S. Dist. LEXIS 131104 (S.D.N.Y. Nov. 14, 2011); *Unison, LLC v. Wooten*, 2011 U.S. Dist. LEXIS 119343 (S.D.N.Y. Oct. 14, 2011).[6]

Defendants do not dispute that Lead Plaintiff has not acted in bad faith, has not unduly delayed seeking leave or that granting leave would not cause undue prejudice. The sole basis for Defendants opposition is the groundless assertion that the proposed amendment is futile. A proposed amendment is futile when it fails to state a claim upon which relief can be granted. *Murphy v. Suffolk County Cmty. College*, 2011 U.S. Dist. LEXIS 136983, 12-14 (E.D.N.Y. Nov. 29, 2011) (*citing Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002)). A determination of futility is governed by the same standards as a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Id*. (internal citation omitted). Under Rule 12(b)(6), the court must accept as true the factual allegations set forth in the complaint and draw all reasonable inferences in favor of plaintiff. *Id*. (internal citations omitted). Defendants bear the burden of establishing the futility of Lead Plaintiff's amendment,

[5] Lead Plaintiff hereby incorporates by reference the Argument section of its Opp. to MTD, except to the extent such arguments are rendered inapplicable by the amended allegations of the PSCAC.

[6] Courts generally grant motions to amend where plaintiff does not seek to add new parties or new claims and where the additions do not alter the substance of the allegations" *ADL, LLC v. Tirakian*, 2010 U.S. Dist. LEXIS 110563 (E.D.N.Y. Aug. 26, 2010).

a burden they have not satisfied. *See Murphy v. Suffolk County Cmty. College*, 2011 U.S. Dist. LEXIS 136983, 5-6 (E.D.N.Y. Nov. 29, 2011) (internal citations omitted).

As such, Lead Plaintiff's Motion should be granted.

A. Amendment of the CAC is Not Futile

The PSCAC easily states a claim under Sections 10(b) and 20(a) of the Exchange Act. The PSCAC is replete with allegations demonstrating that the Company made a series of materially false and misleading statements regarding the conduct of MelaFind's pivotal clinical trial, as well as the safety and efficacy of the device. ¶¶ 25-169. The disclosure of the falsity of these statements at the end of the Class Period caused Mela's share price to plummet, thereby damaging investors. ¶¶ 8, 171. Moreover, the additional allegations in the PSCAC, concerning the restriction on the use of MelaFind to only board certified and specially trained dermatologists, bolster Lead Plaintiff's allegations, as they demonstrate the impact of the trial's undisclosed flaws on the FDA's delayed and severely limited approval of MelaFind. ¶¶ 5-6, 9-10, 31, 35, 41, 45, 48, 71, 114-116, 177, 190. As such, amendment of the CAC is not futile.

B. The Allegations Set Forth in the PSCAC Readily State a Claim Under §10(b)

1. Applicable Standards

To state a claim under §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, a plaintiff must allege that the defendant, in connection with the purchase or sale of a security, made a materially false statement or omitted a material fact, with scienter, and that reliance on defendant's action caused injury to the plaintiff. *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86, 92 (2d Cir. 2010).

2. The PSCAC Adequately Alleges Defendants' Material Misrepresentations

A statement or omission violates Rule 10-b5 when it is "*misleading* as to a *material* fact." *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988). Materiality is "a fact-specific inquiry" that is

not ordinarily resolved on a motion to dismiss. *See ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009); *Ganino v. Citizens Utils. Co*., 228 F.3d 154, 162 (2d Cir. 2000). A misrepresentation or omission is material if it would have "been viewed by the reasonable investor as having significantly altered the total mix of information available." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318 (U.S. 2011). The Second Circuit has repeatedly held that "'a complaint may not properly be dismissed . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance."' *Id*. (citation omitted) (alteration in original). Under these standards, materiality has been more than sufficiently alleged.

The PSCAC alleges in ample detail several undisclosed flaws and Protocol violations in the clinical trial, which severely jeopardized the prospects for a timely and unrestricted FDA approval. Such flaws included: 1) the clinical trial was wholly inadequate for MelaFind's stated indication of use, as the original PMA and Class Period representations stated that the product was intended for use by any "physician (or properly licensed practitioner)," yet the study only included board certified dermatologists; 2) the Company's utilized specious statistical methodologies in order to reach the critical 95% Confidence Interval level for the product's sensitivity; 3) more than 20% of the lesions enrolled in the study were "unevaluable", *i.e.*, lesions which MelaFind could not read--a significant number of which were cancerous melanomas; 4) the Company violated the Protocol by failing to include non-suspicious lesions in the study; and 5) the Company's violated a critical component of the Protocol by failing to conduct a three month follow up study for lesions that were not diagnosed as suspicious for melanoma.

Unable to combat the specific allegations in the PSCAC, Defendants unconvincingly assert futility claiming that they had no duty to disclose, that the delayed and highly restricted "approval" of MelaFind somehow exculpates them in hindsight, and that they are shielded from liability because they issued boilerplate warnings regarding the prospects for FDA approval during the Class Period. These frail arguments are simply unable to mask the simple fact that Lead Plaintiff has adequately alleged numerous critical flaws in the conduct and analysis of the phase III clinical trial, of which Defendants had an undeniable duty to disclose to investors. Amendment of the CAC is therefore not futile.

a) Defendants Violated Their Duty to Disclose

Defendants contend that the material flaws in the clinical study alleged in the PSCAC are mere omissions, which they had no duty to disclose. Def. Br. at 24. However, both parties agree that once a party speaks regarding a matter, it has a duty to speak fully and truthfully. *Matrixx*, 131 S. Ct. at 1323 (noting that "companies can control what they have to disclose under [§ 10(b) and Rule 10b-5(b)] by controlling what they say to the market."); *In re Amylin Pharms., Inc. Sec. Litig.*, No. 01 cv 1455 BTM (NLS), 2002 U.S. Dist. LEXIS 19481, at *14 (S.D. Cal. Oct. 9, 2002) (*Amylin I*) ("While the court agrees that the FDA approval process is highly uncertain and drug companies engage in a 'continuous dialogue' with regulators, Amylin was also under no obligation to make statements regarding the 'completeness' of the trials or the likelihood for FDA approval."); *vacated in part*, No. 01 cv 1455 BTM (NLS), 2003 U.S. Dist. LEXIS 7667 (S.D. Cal. May 1, 2003) (*Amylin II*).

Here, Defendants chose to speak about the conduct and results of its clinical trial. Once the Company began to affirmatively tout its "***positive top line results***" and that the "***trial satisfied the specifications of the Protocol Agreement,***" Defendants had a clear duty to disclose the study's inherent flaws and deviations from the Protocol. These flaws and Protocol deviations

severely threatened the Company's prospects for receiving a timely and unrestricted FDA approval. Moreover, once the Company disclosed its receipt of the March 2010 Non-Approvable Letter, it had a duty to disclose the serious concerns raised by the FDA, rather than tout the study's conformance with the "***agreed upon endpoints***". ¶¶ 40, 153. The disclosure of these significant flaws in the clinical study would have clearly been viewed by the reasonable investor as having significantly altered the "total mix" of information available.

b) The Highly Restricted FDA Approval Does Not Provide Exculpation by Hindsight

Defendants further advance the ridiculous notion that the *post hoc* FDA approval somehow absolves them in hindsight from their § 10(b) violations. Defendants argue that the belated FDA approval for MelaFind, albeit a severely restricted approval for a scant percentage of the original intended target market, proves that the pivotal trial did not contain any Protocol violations. Defendants further contend that their statements regarding the clinical trial could not have been materially misleading, because MelaFind was ultimately approved by the FDA. Such logic doesn't carry water. Under § 10(b) Defendants' statements are not viewed with the benefit of hindsight, ***but rather by the relevant facts available to Defendants at the time such statements are made.*** Indeed, just as "fraud by hindsight" cannot rise to a § 10(b) violation, so too Defendants cannot seek to exculpate themselves from liability by pointing to events that occurred nearly a year after the end of the Class Period. *Fla. State Bd. of Admin. v. Green Tree Fin. Corp*., 270 F.3d 645, 662 (8th Cir. Minn. 2001) ("[j]ust as we cannot countenance pleading fraud by hindsight, neither can we infer innocence by hindsight."). Simply put, "exculpation by hindsight" is not a viable defense under § 10(b).

Moreover, FDA approval—however limited-- does not ipso facto prove an absence of Protocol violations. Indeed, the agency's *Perspectives on Clinical Studies for Medical Device Submissions* states:

> The design, conduct, and analysis of clinical studies are crucial elements in the submission process for premarket approval. . . . The process has few shortcuts, and failure to adhere to sound clinical study design principles is costly[,]" leading to "***delays in the product approval process when the deficiencies resulting from such short cuts induce one or more fatal flaws***."

¶ 39. (emphasis added). Thus, the FDA warns that a violation of a Protocol will likely result in ***delay, not necessarily a wholesale rejection*** of a PMA.

To support their misguided theory, Defendants cite to 21 U.S.C. § 360e(d)(2)(A)-(B), a regulation that does not even mention the word "protocol" and indeed supports Lead Plaintiff's proposition that the Phase III trial did not convince the FDA that MelaFind was safe and effective for use by non-dermatologists. Def. Br. at 25. The provision is clear that approval will be denied if there is a "lack of showing of reasonable assurance that such device is [safe and effective] ***under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.***" This regulation in no way implies, as Defendants suggest, that the FDA will deny approval of a drug or device *in toto* if there are deviations from a binding protocol. Here, however, due to the trial's numerous Protocol violations and other flaws, the FDA did not have "reasonable assurance" that MelaFind was safe and effective for use by non-dermatologists and thus limited its approval of MelaFind to specially trained dermatologists, a mere 1.2% of its intended market. Indeed, Defendants will have the Court believe that the November 1, 2011 FDA "approval" was a victory for the Company and a vindication of the conduct of the clinical trial. To the contrary, in light of the FDA and Panel Members' comments at the Panel Meeting, the Company recognized that FDA would simply refuse to approve the device for the broader

non-dermatological market. Therefore, the Company revised its PMA in March 2011 to restrict the device's use to board certified dermatologists, in an attempt to salvage at least some market—however slim—for the device. Thus, the FDA's restricted approval of the device represented a stunning defeat for the Company, which only bolsters Lead Plaintiff's allegations.

c) The Inapplicability of the PSLRA's Safe Harbor

The PSCAC (as well as the CAC) alleges that Defendants sought FDA approval for use of MelaFind by a wide range of health care professionals, not just dermatologists. However, by only including board certified dermatologists in the trial, Defendants rendered it impossible for the FDA to measure MelaFind's efficacy in the hands of non-dermatologist health care professionals. ¶¶ 49-51. Moreover, as noted *supra*, the trial's other flaws also made it highly unlikely that MelaFind would be approved for non-dermatologists, given the lack of data regarding MelaFind's sensitivity. Nevertheless, Mela unambiguously stated in both Class Period 10-Ks that it intended: "To enter the larger general dermatology and ***primary care*** markets in the US." (Emphasis added). The 10-Ks went on to say:

> In addition, we believe that MelaFind® has significant potential among primary care physicians, who are at the front line of early detection. Currently, primary care physicians do not receive specialized training in the evaluation of pigmented skin lesions. We believe that MelaFind® can greatly assist primary care physicians in their evaluation.

In opposing the Motion, Defendants do not argue that these statements were not false when made but rather assert in a footnote that they are protected by the PSLRA's safe harbor. Def. Br. at 27 n.14. The PSLRA's safe harbor, however, is narrow in scope, applying only to forward-looking statements accompanied by meaningful cautionary language. 15 U.S.C. §78u-5(c)(1). The safe harbor does not apply to statements of present or historical facts, such as those

statements regarding the conduct of MelaFind's Phase III trial. *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 568 (S.D.N.Y. 2011).

Even if the Court were to consider any of Mela's statements forward-looking, Defendants have the burden of demonstrating that the statements were accompanied by meaningful cautionary language. *See Slayton v. Am. Express Co.*, 604 F.3d 758, 773 (2d Cir. 2010). "In order to be effective, cautionary language needs to warn of, or directly relate to, the risk that brought about the plaintiff's loss." *In re Nokia Oyj (Nokia Corp.) Sec. Litig.*, 423 F. Supp. 2d 364, 400 (S.D.N.Y. 2006). Defendants have not carried their burden.

With regard to cautionary language, Mela claims it adequately warned investors that FDA approval was not guaranteed and that Mela could not predict the outcome or the timing of the FDA review. Def. Br. at 2-5, 8-10, 21-2, 26-7.[7] However, such boilerplate warnings are found in every pharmaceutical company's financials, and did nothing to alert investors to the serious flaws in the Company's clinical trial. Here, Mela issued a litany of generally applicable risk factors regarding the potential FDA approval of MelaFind when, at the time of issuing these warnings, information and facts were present that seriously undermined Mela's chances for a full and timely FDA approval. Further, the Complaint alleges that Defendants touted the study's "***positive top line results***" which "***satisfied the specifications of the Protocol Agreement,***" while fully aware of the trial's flaws and deviations from the Protocol Agreement—yet no meaningful

[7] "The majority of alleged misrepresentations here are not forward-looking, and those that can be characterized as such, do not include sufficient cautionary language. While it is argued that investors were repeatedly warned that ImClone's business was 'subject to regulation primarily by the FDA,' that '[n]oncompliance with applicable requirements can result in refusal to approve product licenses or other applications,' that there are 'risks and uncertainties associated with completing pre-clinical and clinical trials ... [and] obtaining and maintaining regulatory approval for such compounds,' and that 'actual results may differ materially' from those predicted, this language is not sufficient to place these statements under the 'safe harbor' provisions of the PSLRA." *ImClone*, 2003 U.S. Dist. LEXIS 9342, at *3-*4. The language rejected as not meaningful in *ImClone* is strikingly similar to Mela's boilerplate risk disclosures.

cautionary language warned investors of such risks, flaws, or concerns raised by the FDA. ¶¶ 117, 119, 132, 148, 153, 158. As such, Mela's meaningless boilerplate warnings that the FDA "may not" grant approval to the device, without any warnings of the study's existing serious flaws, failed to provide investors with critical information regarding their investment in Mela. *See Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004) ("Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired.").

3. The PSCAC Adequately Pleads Scienter[8]

The allegations here raise a strong inference of recklessness, at minimum, by Defendants, which is far more plausible than any competing exculpatory inference. The Complaint cogently alleges Defendants' (i) "knowledge of facts or access to information contradicting their public statements," *Novak*, 216 F.3d at 308; (ii) "[a]n egregious refusal to see the obvious, or to investigate the doubtful," *In re Carter-Wallace Sec. Litig.*, 220 F.3d 36, 40 (2d Cir. 2000); or (iii) failure "to review or check information they had a duty to monitor." *Novak*, 216 F.3d at 308.

a) The PSCAC Adequately Alleges Defendants' Recklessness

The PSCAC is replete with well-founded allegations that there were egregious flaws in the MelaFind study which violated several provisions of the Protocol. Such flaws included: 1) the clinical trial was wholly inadequate for MelaFind's stated indication of use, as the original PMA—as well as the Company's Class Period statements -- stated that the product was to be used by any "physician (or properly licensed practitioner)," but the study only included board certified dermatologists; 2) the Company utilized specious statistical methodologies in order to reach the critical 95% Confidence Interval level for the product's sensitivity; 3) more than 20% of the lesions enrolled in the study were "unevaluable," *i.e.*, lesions which MelaFind could not

[8] The legal standard for establishing scienter in a § 10(b) action is more fully set forth in the Opp. to MTD, 31-32.

read--a significant number of which were cancerous melanomas; 4) the Company violated the Protocol by failing to include non-suspicious lesions in the study; and 5) the Company violated a critical component of the Protocol by failing to conduct a three month follow up study for atypical lesions that were not diagnosed as suspicious for melanoma. Despite such blatant deviations from the Protocol, Defendants continuously touted the study's "***positive top line results***" which "***satisfied the specifications of the Protocol Agreement***.", as well as its potentially broad market of "***primary care physicians***". ¶¶ 117, 119, 120, 128, 132, 136, 143, 147, 148. Such statements were made in both Class Period 10-Ks, which were signed by all of the Individual Defendants, as well in the Company's 10-Q's, which were signed by Defendants Gulfo and Steinhart, respectively the CEO and CFO of Mela. ¶¶ 18-20, 119, 128, 136, 143, 147, 155, 164, 167. *See In re Lattice Semiconductor Corp. Sec. Litig.*, No. CV04-1255-AA, 2006 U.S. Dist. LEXIS 262, at *50 (D. Or. Jan. 3, 2006) (certification relevant to determination of sufficiency of scienter allegations); *Atlas Air*, 324 F. Supp. 2d at 489, (knowledge of false financial statements can be imputed to key officers of the company).

Moreover, Defendants continued to tout the conduct and results of the study even after receiving the FDA's non-approvable letter in March 2010 raising serious concerns about the phase III trial. As such, the Complaint is rife with allegations of Defendants' "conscious misbehavior or recklessness" — that Defendants "engaged in deliberately illegal behavior," "knew facts or had access to information suggesting that their public statements were not accurate" or "failed to check information they had a duty to monitor." *Novak*, 216 F.3d at 308, 311.

Indeed, it is simply inconceivable that Defendants, senior officers of Mela, who were intimately involved in the clinical trial for the Company's flagship product, on whose success the

entire future of Mela depended, were unaware of the study's severe departures from the Protocol, as well its grossly inadequate statistical analysis. *Cosmas v. Hassett*, 886 F.2d 8, 12-13 (2d Cir. 1989) (scienter adequately alleged when a company's directors emphasized the importance of the Chinese market as a new source of revenue, while failing to disclose recently-enacted import restrictions); *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 490 (S.D.N.Y. 2004) ("if facts that contradict a high level officer's public statements were available when the statements were made, it is reasonable to conclude that the speaker had intimate knowledge of those facts or should have known them"); *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 199 (S.D.N.Y. 2010)(finding scienter where misstatements concerned a "core operation" of the company); *Atlas Air*, 324 F. Supp. 2d at 489 ("Accordingly, if a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company."). Indeed, it "strains credulity" that Mela's top executives were unaware of the numerous flaws and Protocol violations plaguing the study, which severely jeopardized any chance of a timely and complete FDA approval.

b) The Lukewarm Panel Vote and Limited FDA Approval Further Affirm Defendants' Scienter

Defendants seek to exculpate themselves from the PSCAC's cogent allegations by pointing to the November 2011 FDA approval of MelaFind. To the contrary, the highly limited approval granted for the device only reinforces the allegations against Defendants. Defendants ignore the fact that the Class Period PMA proposing MelaFind's use by non-dermatologists was gutted by the Company, as a direct result of the FDA's concerns regarding the conduct of and Protocol violations in the clinical trial. Indeed, while the FDA did approve the product for

properly trained board certified dermatologists, representing a scant 1.2% of the market touted to investors, it was not approved for use by 98.8% of its stated potential market. Such a "ringing endorsement" hardly provides Defendants with the exculpation in hindsight that they so desperately seek.

Moreover, Defendants incredibly argue that the "favorable" Panel vote somehow negates an inference of scienter. Def. Br. at 22-3. In the first instance, Defendants falsely represent that such a recommendation came from a majority of the Panel. *Id*. at 2, 12. However, it was only due to the abstention of two Panel members on the vote regarding MelaFind's efficacy, and one abstention regarding the risk versus benefit of MelaFind that the Company achieved a favorable vote. ¶ 46. Indeed, as one panelist admitted, his abstention reflected his ***"overall intuition to vote no."*** As such, the fact that MelaFind only received a Panel recommendation by the slimmest of margins, and only with the assistance of three critical abstentions, indicates that the Panel had serious concerns regarding the conduct of the trial and safety of the device, as well as its proposed indications of use for non-dermatologists, all of which were undisclosed to investors during the Class Period.

In sum, the allegations support a strong inference of scienter that is at least as plausible as any opposing inference.

c) Motive and Opportunity

Courts have upheld motive allegations where defendants were charged with concealing adverse information in circumstances where "the executives' careers and the very survival of the company were on the line." *In re Cabletron Sys*., 311 F.3d 11, 39 (1st Cir. 2002); *see also Aldridge v. A.T. Cross Corp*., 284 F.3d 72, 83 (1st Cir. 2002) (officers understood that the success of new products "was important to their own survival and that of the company").

Mela's viability is tied to the development, manufacture, marketing, and ultimate success of MelaFind. It is undisputed that Mela is critically dependent on the successful commercialization of MelaFind to as large a target market as possible. Without sufficient profits from sales of MelaFind, the prospects of the Company are doomed. Moreover, the Company needed to convince investors of the likelihood of an unrestricted FDA approval, in order to raise vital capital during the Class Period. ¶ 114, 170. As such, it simply could not disclose to investors the numerous flaws plaguing its clinical study. *See Howard v. Everex Sys.*, 228 F.3d 1057, 1064 (9th Cir. 2000) (allegation that CEO potentially had a motive to inflate sales to raise financing for company is probative); *Darquea v. Jarden Corp.*, No. 06 cv 0722 (CLB), 2007 U.S. Dist. LEXIS 40247, at *27 (S.D.N.Y. 2007) (motive to artificially inflate stock price to convert preferred stock to common stock to lift restrictions on the company's ability to raise funds is indicative of scienter), aff'd after recons. based on *Tellabs*, 2007 U.S. Dist. LEXIS 65739 (S.D.N.Y. Sept. 4, 2007). Motive is therefore adequately alleged here.

Defendants argue that scienter is rebutted because the Individual Defendants purchased more shares than they sold during the Class Period. However, a net increase in company holdings does not negate scienter here. *Wachovia Equity Secs. Litig. v. Wachovia Corp.*, 753 F. Supp. 2d 326, 349 (S.D.N.Y. 2011); *In re Ashanti Goldfields Sec. Litig.*, Civ. A. No CV 00-0717 (DGT), 2004 U.S. Dist. LEXIS 5165, at *14-15 (E.D.N.Y. Mar. 30, 2004) (holding that defendants' purchases of stock did not negate an inference of scienter on a motion to dismiss). Indeed, far from negating an inference of scienter, the fact that Individual Defendants purchased shares during the Class Period simply indicates that they thought the fraud would succeed and they would be able to sell their shares at a more inflated price in the future. *See, e.g.*, *Freudenberg*, 712 F. Supp. 2d at 201 (where a defendant may have believed that he could

eventually sell his shares at a profit by continuing to hide the fraud or by resolving undisclosed problems without the public learning of the true facts, courts refuse to hold that defendants' stock purchases were inconsistent with fraud). The cases Defendants cite to the contrary are inapposite. Stock purchases during the Class Period have only undermined allegations of scienter where such allegations were predicated solely on defendants' motive to inflate the price of company stock in order to profit from stock sales. Here, Plaintiff's motive allegations merely supplement the myriad cogent scienter allegations discussed above.

4. The PSCAC Adequately Alleges Loss Causation

In *Dura*, the Supreme Court held that at the pleading stage, a plaintiff must allege loss causation and economic loss sufficient to provide defendants with an "indication of the loss and the causal connection that the plaintiff has in mind." *Id*., 544 U.S. at 347. The *Dura* Court further "conceded" that such allegations need only be pleaded pursuant to Rule 8(a)(2). *Id*. at 346. Loss causation "is typically shown by the reaction of the market to a 'corrective disclosure' which reveals a prior misleading statement." *In re Vivendi Universal, S.A., Sec. Litig*., 765 F. Supp. 2d 512, 555 (S.D.N.Y. 2011). Here, the PSCAC alleges that on November 16, 2010, upon the publication of the FDA's criticisms of the MelaFind trial, the Company's share price fell 54%, on unusually high trading volume. Such allegations provide Defendants with ample "indication of the loss and the causal connection that the plaintiff has in mind."

Defendants argue that the loss causation allegations in the PSCAC are premised on predictions from analysts that MelaFind would be rejected by the FDA, which ultimately proved to be false. Def. Br. at 28. Defendants misstate the record. The quotes from analysts in the PSCAC specifically note that Melafind "***has not been studied adequately for its current indications of use***" and that ***"the outlook for the device known as MelaFind isn't good".*** PSCAC ¶¶ 172, 174. Such predictions turned out to be remarkably prescient. The outlook for

MelaFind, whose potential market has been cut by nearly 99%, certainly is not good, as reflected by its current share price of $4.35, well below its pre-disclosure price of $6.37. The reason for the device's poor prospects is precisely because Melafind had "not been studied adequately" for its proposed indications of use, as demonstrated s*upra*. As such, Defendants challenges to the PSCAC's loss causation allegations do not withstand scrutiny.

CONCLUSION

For the foregoing reasons, Lead Plaintiff requests that the Court grant its Motion for Leave to Amend the Consolidated Amended Complaint.

Dated: February 8, 2012

Respectfully submitted,

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